

Remarks

Claims 1-30 are present in the application. Claims 14-30 have been withdrawn as being directed to a non-elected species. Claims 22 and 23 have been amended to correct obvious matters of form.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph. Applicants respectfully traverse the rejection and request reconsideration thereof.

The Examiner has indicated that the terms “faster, relative, organized, useful and properties” all are vague. Applicants respectfully disagree. Applicants respectfully submit that in order to determine whether or not a word is “vague” one cannot make this determination in a vacuum. Rather, Applicants respectfully submit that to ascertain the meaning or scope of a word to determine whether or not a claim particularly points out and distinctly claims the subject matter Applicant regards as the invention, one must examine the term in view of the disclosure of the application. It is the specification that determines the meaning and scope of words in a claim.

Applicants respectfully submit that each of the above-noted terms, when fairly construed in light of the specification by one skilled in the art of implantable tissue scaffolds that facilitate tissue growth in, e.g. the repair of muskoskeletal tissue, is not vague and that the claims including these terms thus does particularly point out and distinctly claim the subject matter that Applicants regards as the invention.

With regards to “faster”, Applicants respectfully submit that the claim clearly states that fiber A degrades “faster” than fiber B. The term is used in the claims and specification according to its common meaning. No special meaning has been inferred or explicitly stated with respect to “faster”. In other words, one fiber is degraded more rapidly than the other by the body once placed in the body, or the rate of biodegradability of one fiber is greater than the other when placed in the body.

Applicants submit that the claim particularly points out and claims that one fiber degrades faster, more rapidly, quicker, first, or any other commonly used descriptor to indicate the relative speed of some action between two objects. Applicants further note Figure 4 and the specification at page 28, line 1-13 as to a further description. Accordingly, Applicants respectfully submit that “faster”, as used herein, is not vague.

With regards to “relative”, the claim clearly points out and claims relative “amounts”, e.g. weight ratio. The respective amounts of fibers A and B are relative to

each other. This is discussed, for example, at page 7, line 24 to page 8, line 4. Other examples of relative amounts may be gleaned from the examples in the specification. In view of the specification Applicants respectfully submit that the term relative to describe amounts of fiber A and B with respect to each other is not vague.

With regards to “organized”, Applicants respectfully submit that this term is described in detail at, for example, page 5, line 26 to page 7 line 22, as well as in the various examples. The term is described not only with respect to the relative amounts and the structure of the matrix, but also as to response by tissue to the scaffold that is sought to be enhanced by the invention. As further disclosed therein, specific embodiments of organized networks are disclosed, as well as methods of making such organized constructs. In addition, the figures lend further guidance as to the organization of the fibers in the device. Accordingly, Applicants respectfully submit that the term organized, as used in the claims, is not vague.

With regards to “useful”, Applicants respectfully submit that the claims distinctly point out and claim that the implant is useful in the repair and regeneration of mammalian tissue. This is all that is required of 35 U.S.C. 112, second paragraph. In particular, the implant is useful in the repair and regeneration of muskoskeletal tissue. If the Examiner is questioning utility of the implants, utility clearly is supported by the examples and is further exemplified in the Figures. Applicants are not required to explain the theory of how something works, only to provide an enabling description of the invention, provide the best mode and distinctly point out and claim the invention. Applicants respectfully submit that they have met this criteria.

With regards to properties, the specification provides a detailed description of properties useful for the repair and regeneration of mammalian tissue. As noted at page 4, line 19 to page 5, line 18, properties include, for example, biodegradability, resorption, structural integrity over time and the ability to facilitate tissue in-growth. The properties are discussed throughout the application and are exemplified in the examples. When construed in light of the specification, which Applicants maintain one must do under 35 U.S.C. 112, second paragraph, Applicants respectfully submit that one skilled in the art of tissue scaffolds for use in repair and regeneration of tissue would be able to readily ascertain the properties useful for repair and regeneration of mammalian tissue.

Based on all of the foregoing, Applicants respectfully submit that the terms “faster, relative, organized, useful and properties”, when construed in light of the specification, are not vague and that the claims particularly point out and claim Applicants’ invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. 112, second paragraph be withdrawn.

Claims 1-13 are rejected under 35 U.S.C. 102(b) over Dorigatti et al (US 5,520,916). In view of the amendment Applicants respectfully request reconsideration of the rejection.

Claims 1-13, as amended, are directed to an implantable device that comprises a fibrous matrix comprising first fibers A and second fibers B, wherein fibers A and B are selected from a biodegradable polymer selected from the group consisting of aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), polyorthoesters, polyoxaesters, polyamidoesters, poly(anhydrides) and polyphosphazenes.

Dorigatti discloses a fabric material that is useful in surgery for the guided regeneration of tissue. The fabric comprises a matrix having fibers embedded therein, each of which may be an ester of hyaluronic acid. At least one of the matrix or thread must comprise hyaluronic acid according to Dorigatti.

As claims 1-13 are directed to fibers A and B, each of which must be selected from polymers as claimed. As Dorigatti requires that at least one of fibers A and B must comprise an ester of hyaluronic acid, Applicants respectfully submit that Dorigatti fails to anticipate the claims. Furthermore, as Dorigatti requires the presence of an ester of hyaluronic acid ester, Applicants respectfully submit that the claims are not obvious over Dorigatti. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. 102(b) over Dorigatti be withdrawn.

Based on all of the foregoing, Applicants respectfully submit that claims 1-13 are patentable both under 35 U.S.C. 112, second paragraph and 35 U.S.C. 102 and

103 over Dorigatti. Applicants further respectfully submit that claims reading on nonelected species are patentable and earnestly request a notice of allowance with respect to claims 1-30.

Respectfully Submitted,



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